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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/595,126

02/27/2006

Mark Jozef Albert Waer

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10/26/2007

CLARK & ELBING LLP
101 FEDERAL STREET
BOSTON, MA 02110

EXAMINER

YOUNG, SHAWQUA

ART UNIT

PAPER NUMBER

1626

NOTIFICATION DATE

DELIVERY MODE

10/26/2007

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

Office Action Summary

Application No.

10/595,126

Applicant(s)

WAER ET AL.

Examiner

Shawquia Young

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-17 and 19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-17 and 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 February 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- * a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 13-17 and 19 are currently pending in the instant application.

Claims 1-12, 18 and 20-27 have been cancelled by applicants during the prosecution of the instant application.

Prosecution on the merits of this application is reopened on claims 13-17 and 19 considered unpatentable for the reasons indicated below:

There is prior art that was found by the Examiner that reads on the claims 13-17 and 19.

I. **Priority**

The instant application is a 371 of PCT/BE04/00124, filed on August 27, 2004, which is a CIP of 10/651,604, filed on August 29, 2003 now PAT 7,276,506 and claims benefit of Foreign Application UNITED KINGDOM 0408955.3, filed on April 22, 2004.

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The later-filed application must be an application for a patent for an invention, which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No.10/651,604 fails to

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provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Specifically, claims 13-17 and 19, which do not find support in the original disclosure of 10/651,604. There are no examples found in the originally filed disclosure of 10/651,604 for the species listed in claim 13 of the instant application. While there are a genus compound and specific species of compounds found in the specification and the claims of 10/651,604 but the genus compound and species do not provide support for the species of claim 13 in the instant application since these specific compounds of claim 13 in the instant application can only provide support for themselves and are not supported by a broad genus compound which encompasses other combinations and compounds.

Accordingly, claims 13-17 and 19 are not entitled to the benefit of the prior application, 10/651,604. Applicants will receive the priority date of the Foreign Application UNITED KINGDOM 0408955.3, filed on April 22, 2004.

II. Rejections

35 USC § 103 - OBVIOUSNESS REJECTION

The following is a quotation of 35 U.S.C. § 103(a) that forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Graham v. John Deere Co. set forth the factual inquiries necessary to determine obviousness under 35 U.S.C. §103(a). See *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). Specifically, the analysis must employ the following factual inquiries:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

(1) Claim 13 is rejected under 35 U.S.C. § 103(a) as being unpatentable over *Matter, et al.* Applicants claim a pteridine derivative selected from the group consisting of various species that include 2-amino-4-morpholino-6-(4-ethoxyphenyl)pteridine, 2-amino-4-morpholine-6-(4-propoxy-phenyl)pteridine and 2-amino-4-morpholino-6-(4-butoxy-phenyl)-pteridine.

The Scope and Content of the Prior Art (MPEP §2141.01)

The *Matter, et al.* reference teaches 4-amino-pteridine compounds as nitric oxide synthase inhibitors that include 2-amino-4-morpholino-6-(4-methoxyphenyl)pteridine (See ID 313 on page 2925).

The Difference Between the Prior Art and the Claims (MPEP §2141.02)

The difference between the prior art of *Matter, et al.* and the instant invention is that the applicants are claiming derivatives with an alkoxy substituent (ethoxy, propoxy and butoxy) attached to the phenyl ring in the 6-position of the pteridine core excluding methoxy.

Prima Facie Obviousness-The Rational and Motivation (MPEP §2142-2413)

In In re Henze, 85 U.S.P.Q. 261,263 (C.C.P.A. 1950), it was well established that adjacent homologs are considered to be obvious absent unexpected results. A pteridine derivative with a methoxy substituent attached to the pheny ring in the 6-position of the pteridine core was already known in the prior art and simply changing the substituent to other alkoxy groups is obvious and will lead to a reasonable expectation of success. Therefore, one of ordinary skill in the art would have been motivated to prepare the instantly claimed species of 2-amino-4-morpholino-6-(4-ethoxyphenyl)pteridine, 2-amino-4-morpholine-6-(4-propoxy-phenyl)pteridine and 2-amino-4-morpholino-6-(4-butoxy-phenyl)-pteridine.

(2) Claims 13-17 and 19 are rejected under 35 U.S.C. § 103(a) as being unpatentable over *Waer, et al.* (US Patent No. 7,276,506). Applicants claim a pteridine derivative selected from the group consisting of various species that include 2-amino-4-morpholino-6-(4-ethoxyphenyl)pteridine, 2-amino-4-morpholine-6-(4-propoxy-phenyl)pteridine, 2-amino-4-morpholino-6-(4-butoxy-phenyl)-pteridine, 2-amino-4-(4-methyl-piperidine)-6-[[3,4-(dimethoxyphenyl)]pteridine, 2-amino-4-((*R*)-sec-butylamine)-6-[[3,4-dimethoxyphenyl]pteridine and 2-amino 4-((*S*)-sec-butylamine)-6-[[3,4-dimethoxyphenyl]]pteridine.

The Scope and Content of the Prior Art (MPEP §2141.01)

The *Waer, et al.* reference teaches pteridine derivatives with immunosuppressive effects that includes 2-amino-4-morpholino-6-(4-methoxyphenyl)pteridine (See example 23), 2-amino-4-piperidino-6-(3,4-dimethoxyphenyl)pteridine (See example 28) and 2-amino-4-propylamino-6-(3,4-dimethoxyphenyl)pteridine (See example 51) .

The Difference Between the Prior Art and the Claims (MPEP §2141.02)

The difference between the prior art of *Waer, et al.* and the instant invention is that the applicants are claiming derivatives with an alkoxy substituent (ethoxy, propoxy and butoxy) attached to the phenyl ring in the 6-position of the pteridine core ring instead of methoxy group. Applicants are also claiming a derivative with a methyl group attached to the piperidine ring in the 4-position of the pteridine core instead of an unsubstituted piperidine ring and a derivative with a sec-butylamine in the 4-position of the pteridine core ring instead of a propylamine.

Prima Facie Obviousness-The Rational and Motivation (MPEP §2142-2413)

In *In re Henze*, 85 U.S.P.Q. 261,263 (C.C.P.A. 1950), it was well established that adjacent homologs are considered to be obvious absent unexpected results. A pteridine derivative with a methoxy substituent attached to the phenyl ring in the 6-position of the pteridine core was already known in the prior art and simply changing the substituent to other alkoxy groups is obvious and will lead to a reasonable expectation of success. The same reasoning is used in discussing the sec-butyl amine group of the

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derivatives 2-amino-4-((*R*)-sec-butylamine)-6-[[3,4-dimethoxyphenyl]pteridine and 2-amino 4-((*S*)-sec-butylamine)-6-[[3,4-dimethoxyphenyl]]pteridine in the instant claims and the propyl amine group of the 2-amino-4-propylamino-6-(3,4-dimethoxyphenyl)pteridine in the prior art reference. Therefore, one of ordinary skill in the art would have been motivated to prepare the instantly claimed species of 2-amino-4-morpholino-6-(4-ethoxyphenyl)pteridine, 2-amino-4-morpholine-6-(4-propoxyphenyl)pteridine, 2-amino-4-morpholino-6-(4-butoxyphenyl)-pteridine, 2-amino-4-((*R*)-sec-butylamine)-6-[[3,4-dimethoxyphenyl]pteridine and 2-amino 4-((*S*)-sec-butylamine)-6-[[3,4-dimethoxyphenyl]]pteridine.

In *In re Druey*, 319 F. 2d 237, 138 U.S.P.Q. 39 (C.C.P.A. 1963), it was well established that the substitution of methyl for hydrogen on a known compound is not a patentable modification absent unexpected or unobvious results. Replacing hydrogen with methyl usually does not result in a significant difference in biological activities. A pteridine derivative with an unsubstituted piperidine ring in the 4-position of the pteridine core was already known in the prior art and simply attaching a methyl group to the piperidine ring would be considered obvious and would lead to a reasonable expectation of success. Therefore, it would have been prima facie obvious to one having ordinary skill in the art at the time the invention was made to prepare 2-amino-4-(4-methyl-piperidine)-6-[[3,4-(dimethoxyphenyl)]pteridine.

III. Conclusion

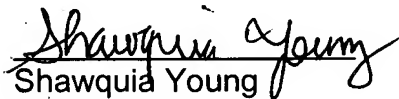
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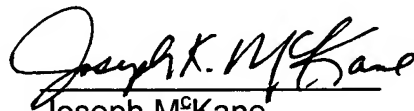
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the examiner should be directed to Shawquia Young whose telephone number is 571-272-9043. The examiner can normally be reached on 6:30 AM-3:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph M^cKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Shawquia Young
Patent Examiner
Art Unit 1626, Group 1620
Technology Center 1600


Joseph M^cKane
Supervisory Patent Examiner
Art Unit 1626, Group 1620
Technology Center 1600